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SIPDIS

DEPT FOR OES/EID NCARTER-FOSTER
FOR OES/IHA JKAUFMAN/TGALLAGHER
FOR S/GAC DEPUTY COORDINATOR JOSEPH O'NEILL
HHS FOR FDA
HHS FOR NIH/FOGARTY CENTER

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SUBJECT: AIDS EPIDEMIOLOGY IN ITALY

REFTEL: ROME 3542

1. Summary: More than 100,000 Italians are estimated to be HIV-positive and 51,172 cases of AIDS have been registered from 1982 to December 31, 2002. Cases of AIDS, which are still mainly transmitted through intravenous drug use, have been declining since 1995, as combination therapy for HIV infection became the standard of treatment. However, as in the US, Italian health officials worry that availability of highly effective HIV treatments could lead to a return to risky behaviors and a resurgence of AIDS. The Italian health care system provides universal coverage and assures adequate medical treatment to infected individuals (all infected individuals, whether citizens or not). Italy and the U.S. are cooperating closely in both AIDS research and clinical trials. End summary.

GOI'S AIDS ACTION PLAN

2. In June 1990, the Italian parliament approved Law 135, the GOI's action plan against AIDS. The plan included numerous research and training initiatives, as well as prevention measures and assistance improvements. In particular, Law 135 defined an extraordinary budget item of USD 75 million over five years for research and prevention initiatives. The Superior Institute of Health (ISS) was the agency responsible for organizing training courses, distributing funds to research institutes, and coordinating therapeutic clinical trials.

3. The law guarantees free medical assistance to HIV-positive patients and assures adequate medical treatment of infected individuals. Because the law was passed when AIDS incidence was growing quickly, it provides for the upgrading and creation of many infectious disease departments, and hiring of specialized personnel.

4. According to Giuseppe Ippolito, Scientific Director of the National Institute for Infectious Diseases, the GOI funds AIDS research in Italy at a level of approximately Euro 10 million per year. This amount does not cover the costs of prevention campaigns, the number of which has decreased over time.

DECREASE IN INCIDENCE HAS HIT FLOOR

5. AIDS is already the leading cause of death among 25-35 year-old Italians. From 1982, when the first Italian AIDS case was diagnosed, to December 31, 2002, a total of 51,172 AIDS cases have been reported to the AIDS operating center (COA), the public health authority in charge of recording all Italian AIDS cases. (Note: The COA belongs to the ISS, which is also responsible for distributing public AIDS funds to research institutes. End note.) Considering under-reporting and delays in reporting to the COA, the actual number of cases is estimated to be higher, around 51,700.

6. The annual AIDS incidence rate increased steadily from 1986 to 1995 (from 0.8 to 10.0 people per 100,000 inhabitants), but then started to decrease sharply, as combination therapy for HIV infection (Highly Active Antiretroviral Therapy - HAART) became the standard of treatment for the disease (5.5 in 1997, 4.0 in 1998, 3.5 in 1999, and 3.2 in 2000). The incidence appears to have stabilized. Total cases in 2002 were roughly equal to total 2001 cases.

INCREASING PERCENTAGES OF WOMEN AND HETEROSEXUALS

7. The highest percentage (71.3 percent) of AIDS cases for both males and females was observed for the age group

25-39 years. Male cases constitute 78 percent of total AIDS cases. Pediatric cases (children under 13 years old) make up 1.5 pct. Foreigners make up 5.8 pct of the cases (2,959 cases). (Note: AIDS incidence among foreigners has increased over time: from 3.0 pct in 1982-93 to 15.4 pct in 2001-2. End note.)

18. The percentage of female patients has also increased, from 16 pct in 1985 to 23.6 pct in 2002. The majority of AIDS cases (61 pct in total prevalence 2002) are among intravenous drug users (59 pct if we do not include the homosexual drug users). However, since 1995, HIV transmission through heterosexual contact is the second most frequent cause of AIDS (38 pct in 2001-2), surpassing homosexual transmission (17 pct in 2001-2). Moreover, the decreasing trend of AIDS incidence is less evident among heterosexuals, who, according to Italian surveys, do not take advantage of early testing and thus early treatment.

19. Out of 725 pediatric cases (age at diagnosis less than 13 years), 554 (93.5 pct) were vertical (mother-child) transmission cases. Thanks to a program of prevention and combination therapy administered to HIV-positive pregnant women, Italy has reported a huge decrease in new pediatric cases since 1997 (from 48 in 1997-98 to 14 in 2001-2).

MORE CASES IN CENTRAL-NORTHERN ITALY

10. A north-south gradient in the diffusion of the disease is evident and has been observed since 1983. AIDS incidence (number of new cases per 100,000 inhabitants per year) is higher in Lombardy (5.6), Lazio (5.4), and Emilia Romagna (4.5). The lowest incidence is observed in Calabria and Molise (0.6), and Sicily (1.3).

11. The COA's AIDS mortality figures continue underestimate the real levels. Reporting of AIDS patients' deaths to the authorities is still not compulsory, but has become more reliable due to a national survey carried out in 2001 on AIDS patients. From 1982 to the end of December 2002, a total of 33,308 AIDS patients died (65.1 pct). The mortality rate (i.e. number of deaths/number of new cases for the same year) has been decreasing: 90 pct in 1992, 79 pct in 1994, 46 pct in 1996, 27 pct in 1998, 18 pct in 2000, and 11.2 pct in 2002.

PREVENTION ONLY SURE WAY TO BRING INFECTION RATES DOWN

12. The AIDS operating center's director, Giovanni Rezza, told us that the sharp decrease in AIDS incidence and mortality in the past three years is not due to a reduction in HIV infections - HIV positive people are estimated to be 80,000-110,000 - but to the effects of combined antiretroviral therapies. Successful HIV prevention programs and early testing for HIV infection are considered critical to bringing infection rates down and reducing new cases of AIDS. As in the United States, Italian health officials worry that availability of highly effective HIV treatments could lead to a return to risky behaviors and a resurgence of AIDS.

U.S.-ITALY COOPERATION ON HIV/AIDS

13. On September 25, 2002, Health Minister Sirchia announced the agreement between the ISS and CHIRON Corporation for the development of a combined, second-generation vaccine against AIDS. Both ISS and CHIRON (co-funded by NIH) have developed their own anti-HIV vaccine and have been independently testing their clinical efficacy. The agreement will allow to develop a combined vaccine, which, joining the single ones, should be more powerful and tested more quickly (within 3-4 years instead of 6-7). The 12-million-Euro costs will be equally shared between the Health Ministry and CHIRON.

14. On July 28, President of ISS Prof. Enrico Garaci and NIH Director Dr. Elias A. Zerhouni signed a Letter of Intent on research cooperation (reftel). The Letter opened the cooperation to a broad range of diseases, including cardiovascular and neurodegenerative diseases, like Parkinson's and Alzheimer's. The cooperation will also focus on vaccine development, especially for

HIV/AIDS. The Italian contribution will be about 7.5 million USD. (Note: The US and Italy are the two largest contributors to the Global Fund - the Fund to fight AIDS, Malaria and Tuberculosis. This bilateral cooperation in vaccine development is a logical extension

of, and a complement to, the broader international effort through the Global Fund, and to President Bush's new initiative to combat HIV/AIDS in Africa. End note.) Sembler

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